

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Camellia W. Adams et al. Serial No.: to be assigned Filed: July 8, 2003 For: HUMAN ANTI-FACTOR IX/IXa ANTI BODIES	Group Art Unit: to be assigned Examiner: to be assigned Express Mail Label No. EV 351 928 092 US Date Mailed: July 8, 2003
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☒ **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
 - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
 - before the mailing of the first Office action on the merits; **or**
 - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- ☐ **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

Serial No. Not Yet Assigned

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/383,667, filed August 26, 1999 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

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In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,

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By:



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PATENT TRADEMARK OFFICE

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1661R2C1	Serial No. not yet assigned
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Adams, Camellia et al.	
				Filing Date 08 Jul 2003	Group not yet assigned

U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	5,654,407	05.08.97	Boyle et al.			

FOREIGN PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	* 2	WO 91/16353	31.10.91	PCT			
	* 3	WO 95/25167	21.09.95	PCT			
	* 4	WO 97/26010	24.07.97	PCT			

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)	
* 5	Ahmad and Walsh, "Platelet membrane-mediated coagulation protease complex assembly" <u>Trends in Cardiovascular Medicine</u> 4(6):271-277 (1994)
* 6	Ahmad et al., "Coagulation factor IX residues G4-Q11 mediate its interaction with a shared factor IX/IXa binding site on activated platelets but not the assembly of the functional factor X activating complex" <u>Biochemistry</u> 37(6):1671-1679 (Feb 10, 1998)
* 7	Ahmad et al., "High-affinity, specific factor IXa binding to platelets is mediated in part by residues 3-11" <u>Biochemistry</u> 33(40):12048-12055 (Oct 11, 1994)
* 8	Bach, R. R., "Initiation of Coagulation by Tissue Factor" <u>CRC Critical Reviews in Biochemistry</u> 23(4):339-368 (1988)
* 9	Benedict et al., "Active site-blocked factor IXa prevents intravascular thrombus formation in the coronary vasculature without inhibiting extravascular coagulation in a canine thrombosis model" <u>Journal of Clinical Investigation</u> 88(5):1760-1765 (Nov 1991)
*10	Blackburn et al., "Anti-factor IX monoclonal antibody, BC2, is a potent antithrombotic agent" <u>Blood</u> (Abstract #1885) 90(Suppl. 1):424a-425a (1997)
*11	Cheung et al., "Identification of the endothelial cell binding site for factor IX" <u>Proc. Natl. Acad. Sci. USA</u> 93(20):11068-11073 (Oct 1, 1996)
*12	Cheung et al., "The binding of human factor IX to endothelial cells is mediated by residues 3-11" <u>Journal of Biological Chemistry</u> 267(29):20529-20531 (Oct 15, 1992)
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*14	Di Scipio et al., "Activation of human factor IX (Christmas factor)" <u>Journal of Clinical Investigation</u> 61(6):1528-1538 (Jun 1978)
*15	Figini et al., "In Vitro Assembly of Repertoires of Antibody Chains on the Surface of Phage by Renaturation" <u>J. Mol. Biol.</u> 239:68-78 (1994)
*16	Fujikawa et al., "The mechanism of activation of bovine factor IX (Christmas factor) by bovine factor XIa (activated plasma thromboplastin antecedent)" <u>Biochemistry</u> 13(22):4508-4516 (Oct 22, 1974)
*17	Heimark and Schwartz, "Binding of coagulation factors IX and X to the endothelial cell surface" <u>Biochemical & Biophysical Research Communications</u> 111(2):723-731 (Mar 16, 1983)
*18	Janeway et al. <u>Immunobiology</u> , Garland Press, 4th edition, London NY pps. 87 (1999)
*19	Lewis et al <u>Blood</u> 56(4):608-614 (1980)

Examiner	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*20	Lewis et al., "Isolation of CA ⁺⁺ -dependent human antibodies to human factor IX" <u>Circulation</u> (abstract #1070) 62(4):III-279 (Oct 1980)				
*21	Liebman et al., "The factor IX phospholipid-binding site is required for calcium-dependent activation of factor IX by factor XIa" <u>Journal of Biological Chemistry</u> 262(16):7605-7612 (Jun 5, 1987)				
*22	Liebman, H., "The metal-dependent conformational changes in factor IX associated with phospholipid binding. Studies using antibodies against a synthetic peptide and chemical modification of factor IX" <u>European Journal of Biochemistry</u> 212(2):339-345 (Mar 1, 1993)				
*23	Limentani et al. <u>Hemostasis and Thrombosis Basic Principles and Clinical Practice, Chapter 5</u> , Coleman et al. Eds., Third edition, Philadelphia:Lippincott Company (1994)				
*24	Mann et al., "Surface-dependent hemostasis" <u>Seminars in Hematology</u> 29(3):213-226 (Jul 1992)				
*25	Osterud and Rapaport, "Activation of factor IX by the reaction product of tissue factor and factor VII: additional pathway for initiating blood coagulation" <u>Proc. Natl. Acad. Sci. USA</u> 74(12):5260-5264 (Dec 1977)				
*26	Osterud et al., "Human blood coagulation factor IX. Purification, properties, and mechanism of activation by activated factor XI" <u>Journal of Biological Chemistry</u> 253(17):5946-5951 (Sep 10, 1978)				
*27	Pike et al., "Immunochemical characterization of a monoclonal γ G4, A human antibody to factor IX" <u>Blood</u> 40(1):1-10 (Jul 1972)				
*28	Prorok et al., "The entire γ -carboxyglutamic acid- and helical stack-domains of human coagulation factor IX are required for optimal binding to its endothelial cell receptor" <u>International Journal of Peptide & Protein Research</u> 48:281-285 (1996)				
*29	Rawala-Sheikh et al., "Role of γ -carboxyglutamic acid residues in the binding of factor IXa to platelets and in factor-X activation" <u>Blood</u> 79(2):398-405 (Jan 15, 1992)				
*30	Refino et al., "A Human Antibody That Binds to the γ -Carboxyglutamic Acid Domain of Factor IX is a Potent Antithrombotic In Vivo." <u>Thrombosis and Haemostasis</u> 82(3):1188-1195 (Sep 1999)				
*31	Reisner et al., "Immunochemical characterization of a polyclonal human antibody to factor IX" <u>Blood</u> 50(1):11-19 (Jul 1977)				
*32	Ryan et al., "Structural determinants of the factor IX molecule mediating interaction with the endothelial cell binding site are distinct from those involved in phospholipid binding" <u>Journal of Biological Chemistry</u> 264(34):20283-20287 (Dec 5, 1989)				
*33	Sekiya et al., "Regulation of the tertiary structure and function of coagulation factor IX by magnesium (II) ions" <u>Journal of Biological Chemistry</u> 270(24):14325-14331 (Jun 16, 1995)				
*34	Spanier et al., "Heparinless cardiopulmonary bypass with active-site blocked factor IXa: a preliminary study on the dog" <u>Journal of Thoracic & Cardiovascular Surgery</u> 115(5):1179-1188 (May 1998)				
*35	Stenflo and Dahlback, "Vitamin K-Dependent Proteins" <u>The Molecular Basis of Blood Diseases</u> , Stamatoyannopoulos et al. eds., 2nd edition, Philadelphia, PA:Saunders pps. 565-598 (1994)				
*36	Suggett et al., "Use of phage display for the generation of human antibodies that neutralize factor IX function" <u>Blood</u> (abstract #2266) 92(10 suppl. 1):551a (Nov 15, 1998)				
*37	Sugo et al., "Anti-human factor IX monoclonal antibodies specific for calcium ion-induced conformations" <u>Thrombosis Research</u> 58(6):603-614 (Jun 15, 1990)				
*38	Toomey et al., "The endothelial cell binding determinant of human factor IX resides in the γ -carboxyglutamic acid domain" <u>Biochemistry</u> 31(6):1806-1808 (Feb 18, 1992)				
*39	Wong et al., "Relative efficacy of active site-blocked factors IXa, Xa in models of rabbit venous and arterio-venous thrombosis" <u>Thrombosis and Haemostasis</u> 77(6):1143-1147 (Jun 1997)				
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